K01 3146

EXHIBIT #1
3 pages

DEC 0 7 2001

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____

1. **Submitter's Identification:**

Viatronix Inc.
25 East Loop Road
Suite 203
Stony Brook, NY 11790

Contact: Baman Pattanayak, Director of QA/RA

Date Summary Prepared:

September 17, 2001

2. **Name of the Device:**

Viatronix V3D Calcium Scoring System

3. **Predicate Device Information:**

1. Netra Workstation and NetraMD Software System, K#003484, SCImage, Los Altos, CA (892.2050, Product Code: 90LLZ)

2. CT Coronary Artery Calcification Scoring Option for Advantage Windows, K#982004, GE Medical Systems, Milwaukee, WI (892.1750, Product Code: 90JAK)

3. VScore Image Processing Software with EKG Signal Gating Option for Cardiac Scoring, K#001682, Vital Images, Plymouth, MN (892.1750, Product Code: 90JAK)

4. **Device Description:**

The V-3D Calcium Scoring System for Coronary Artery Calcification Scoring is an additional image processing option added to our V-3D visualization system for which

pre-market clearance was granted by the FDA vide K#002780, dated November 17, 2000. The V-3D Calcium Scoring is an anatomy specific software module, designed for use as a part of our V-3D visualization system core technology. The system consists of a V-3D processor and a V-3D viewer. Upon receipt of a multi-slice CT scanner image for coronary arteries through DICOM, the V-3D processor converts the DICOM image data into an internally recognized volume data format using our core software technology. The V-3D viewer provides interactive 2D and 3D views from the V-3D viewer and determines the density and location of calcium deposits within the coronary arteries and also scores measurements of calcium deposits. The calcium score provides a quantitative evaluation of the extent of plaque accumulation in the coronary arteries.

The V-3D/Calcium Scoring Software System was designed, developed, tested and validated at the beta site according to written procedures in compliance with FDA 21 CFR Part 820 and CDRH Guidance Version 1.1 on General Principles of Software Validation.

5. **Intended Use:**

The Viatronix V-3D Calcium Scoring System is intended to be used by a trained physician for the review and analysis of CT images as an aid in cardiac analysis.

6. **Comparison to Predicate Devices:**

The Viatronix V3D Calcium Scoring Module has the same technological characteristics as the three predicate devices, the G.E. CACS, the ScImage NetraMD, and the Vital Images VScore. They all provide multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. They all provide color-coded potential plaques and color-coded assigned plaques. They all report scores per artery and total calcium scores. The only difference is that G.E.'s product only computes Agatston score, while Vital Images and ScImages compute both Agatston and Volumetric just like the V3D Calcium Scoring Module.

We conclude that the subject device, the Viatronix V3D Calcium Scoring Module, is as safe and effective as the predicate devices and poses no new questions of safety and effectiveness.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Simulated "phantom" datasets were generated as test input sets for the calcium scoring algorithms as part of the Unit Tests. These datasets contain known values whereby the expected output of the system can be calculated to theoretical precision. These datasets were run through the V3D Calcium Scoring Module and the output results correlated perfectly to the pre-calculated score values.

The V3D Calcium Scoring Module has been developed in a manner consistent with accepted standards for software development, including both unit and system integration testing protocols. Testing on phantom objects has determined its level of accuracy, which correlates perfectly with pre-calculated values from published algorithms. The product has shown itself to be reliable, easy to use and capable of calculating useful Calcium Score values.

We conclude from these tests that V3D Calcium Scoring Module is substantially equivalent to the predicate device in its ability to calculate useful Calcium Score values.

8. **Discussion of Clinical Tests\Evaluations Performed:**

Tests and validations on Patients' Calcium Scoring Cases were performed per protocol. Loaded Patients' Calcium Scoring Cases to the predicate device. Evaluated all Cases using the predicate device and recorded the total volumetric score and the total Agatston score for all arteries.

Same Cases were loaded into the Viatronix V3D Calcium Scoring application. Evaluated all Patients' Calcium Scoring using V3D Calcium Scoring application, and recorded the total volumetric score and the total Agatston score for all arteries.

Statistical t-test and F-test were performed for both the volumetric and Agatston score at a 99% level of confidence on two sets of scores obtained from the predicate device and the V3D Calcium Scoring application. Statistical t-tests concluded that the difference between the means of the two sets of scores is zero or insignificant with a 99% level of confidence, and F-tests concluded that the two sets of scores do not differ in variability with a 99% level of confidence.

In conclusion, it was established that the V3D Calcium Scoring application is substantially equivalent to NetraMD System, K # 003484, SCImage.

9. **Conclusions:**

The Viatronix V3D Calcium Scoring application has the same intended use and similar technological characteristics as the NetraMD System, SCImage (K # 003484), CT Coronary Artery Calcification Scoring option, GEMedical Systems (K # 982004) and VScore Image processing with EKG signed gating option for cardiac scoring, Vital Images (K # 001682). Moreover, tests and validations using Patients' Calcium Scoring Cases and non-clinical tests performed demonstrated that the Viatronix V3D Calcium Scoring application is substantially equivalent to the predicate devices in its ability to review and analyze CT images for the cardiac calcium scoring to facilitate cardiac analysis by a trained physician. The Viatronix V3D Calcium Scoring application does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Viatronix, Inc.
% Ms. Susan Goldstein-Falk
Official Correspondent
Mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K013146
Trade/Device Name: Viatronix V3D Calcium Scoring CT software
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: September 19, 2001
Received: September 20, 2001

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K013146

Device Name: Viatronix V3D Calcium Scoring System

Indications For Use:

The Viatronix V3D Calcium Scoring System is intended to be used by a trained physician for the review and analysis of CT images as an aid in cardiac analysis.

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013146

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)** OR **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**